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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Application Number 1662/52804

Application Number 10/759,573

Invention Title Invention(s)

STABLE GABAPENTIN HAVING pH WITHIN A

Docket Number: 1662/52804

Examiner Simon J. Oh 1618

Inventor(s)

Claude SINGER et al.

Address to

Mail Stop: RCE

CONTROLLED RANGE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

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on Sept-(120)

Signature: Signature:

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- 1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. The references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.
- 2. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
- 3. A copy of each non-U.S. patent, non-U.S. published application, unpublished U.S. application, non-patent publication, or other information listed on the modified PTO form 1449 is enclosed.
- 4. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated:

9/1/05

Ву

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2 Sheet

Complete if Known				
Application Number	10/759,573	70	EX	
Filing Date	January 16, 20	04	1 18	
First Named Inventor	Claude Singer	et aAUGO	X 30/2 R	
Art Unit	1615	III nE	D W	
Examiner Name	Simon J. Oh 🕻	Mary V.	Æ/	
Attorney Docket Number	1662/52804	TRADE	MARK	

	U.S. PATENT DOCUMENTS				
Examiner	Cite	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Initials *	No.1	Number - Kind Code ² (if known)			
		5,095,148	March 10, 1992	Mettler et. al.	
		5,510,381	April 23, 1996	A.C. Pande	
		5,149,870	September 22, 1992	Mettler et al.	
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		6,528,682	March 4, 2003	Bosch Llado et al.	
		6,294,690	· September 25, 2001	Deering et al.	

	FOREIGN PATENT DOCUMENTS					
E		Foreign Patent Document			Pages, Columns, Lines,	
Examin er Initials*	Cite No. ¹	Country Code ³ – Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵
		DE 24 80 891	July 1, 1976	Satzinger et al.		Yes (Abs.)
		EP 0 458 751 A1	Nov. 27, 1991	Cherukuri et al.		
		WO 97/33858	Sept. 18, 1997	Horwell et al.		
		GB 898 692	June 14, 1962	Warner Lambert		
		WO 04/46108	June 3, 2004	Kuppuswamy et al.		
		WO 00/01660	January 13, 2000	Paiocchi et al.		
	1	WO 02/34709	May 2, 2002	Cannata et al.		
		WO 00/39074	July 6, 2000	Gizur et al.		
	1	WO 00/64857	November 2, 2000	Bosch Llado et al		
		WO 99/18063	April 15, 1999	Deering et al.		
	1	WO 96/36328	July 22, 1999	Pande		
	1	WO 92/14443	September 3, 1992	Chaturvedi et al.		

Examiner Signature	Date Considered	

Substitute for form 1449B/PTO			Complete if Known		
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/759,573	
			Filing Date	January 16, 2004	
STAT			First Named Inventor	Claude Singer et al.	
			Art Unit	1615	
	(Use as many sheets as necessa	ry)	Examiner Name	Simon J. Oh	
Sheet	of		Attorney Docket Number	1662/52804	

_		NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Zour et al. "Stability studies of gabapentin in aqueous solutions" <i>Pharmaceutical Research</i> , Vol. 9, No. 5, 1992 pages 595-600	
		USP Monograph for Gabapentin	
		Pharmacopeial Forum, Vol. 25, No. 5, SeptOct. 1999, pages 8711-8717	<u> </u>
		Holder, R.W. et al., "Geminate-Substituted Cyclopentadienes. 1. Synthesis of 5,5-Dialkylcyclopentadienes via 4,4-Dialkylcyclopent-2-en-1-ones", <i>J. Org. Chem.</i> 1982, Vol. 47, pages 1445-1451.	
		Thorpe et al.; paper entitled, "The Formation and Reactions of Imino Compounds: Part XVIII. The Condensation of cycloHexanones with Cyanoacetamide Involving the Displacement of an Alkyl Group. J. Chem. Soc. 1913, pages 1586-1600.	
		Vogel, A.I., paper entitled "Physical Properties and Chemical Constitution: Part II. Esters of ÿÿ-Substituted Glutaric Acids. J. Chem. Soc., 1934, pages 1758-1765	
		Griffiths et al., "Novel Synthesis of Gabapentin via Addition of Hydrocyanic Acid to Cyclolexylidenemalonate or Cyano(cyclohexylidene) acetate," <i>Helvetica Chimica Acta</i> , 74, 309 (1991)	
		Kearney et al., "The Effect of Cyclodextrins on the Rate of Intramolecular Lactamization of Gabapentin in Aqueous Solution," <i>International Journal of Pharmaceutics</i> , 78, 25-34 (1992).	
		Notice of Opposition to A European Patent, No. 1 289 364 of Teva Pharmaceutical Industries Ltd., Opponent: Hikal Limited, 10 December 2003, European Patent Bulletin, pp. 1-4; and Statement of Grounds for Opposition, pp. 1-16.	
		Arrow Generics Limited and Teva Pharmaceutical Industries Limited, Amended Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 00951, 16 March 2004, pp. 1-3.	
		Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Defence and Counterclaim, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-2 and pp. 1-3.	
		Teva Pharmaceutical Industries Ltd. v. Hikal Group Ltd., Civil Action No. 1:05-cv-00691 (ESH), In the United States District Court for the District of Columbia, Answer, Affirmative Defenses, Counterclaim and Jury Trial Demand of Defendants Apotex Corp. and Apotex Inc., May 16, 2005, pp. 1-59.	
		Teva Pharmaceutical Industries Limited and Generics (UK) Limited, Grounds of Invalidity, In the High Court of Justice Chancery Division Patents Court, Case No. HC 04 C 03383, 17 December 2004, pp. 1-3.	
		Request for Examination Under Section 35(1) of the Act and Request for Advanced Examination Under Section 28 of the Rules in Teva Pharmaceutical Industries' Canadian Patent Application No. 2,411,787, to Commissioner or Patents (Canada) by Kirby Eades Gale Baker on May 27, 2005, pp. 2-14, (incl. Appendix A, 12 pages, Appendix B, 1 page, Appendix C, 5 pages.)	
		Complaint, of Teva Pharmaceutical Industries Ltd. against Hexal AG and Salutas Pharma GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.	

Complaint, of Teva Pharmaceutical Industries Ltd. against ratiopharm GmbH and Merckle GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.
Complaint, of Teva Pharmaceutical Industries Ltd. against STADApharm GmbH and STADA Arzneimittel AG, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.
Complaint, of Teva Pharmaceutical Industries Ltd. against Zambon Group SpA (Italy) and Zambon GmbH, Regional Court Dusseldorf, 4 th Civil Chamber, October 20, 2003, pp. 10.
Reply and Counterclaim Brief of Teva Pharmaceutical Industries Limited, and Zambon Group SpA, Court of Milano, Section specialized in intellectual and industrial property matters, Case No. 77571/03, February 7, 2004, pp. 1-14.
Writ of Summons, Court of Milan, Zambon Group SpA and Teva Pharmaceutical Industries Ltd., Milan, December 9, 2003, pp. 1-21.
Brief of Reply for the Plaintiff, Court of Milano, Section Specialized in Industrial Right I.J. Dr. Migliaccio In the Lawsuit No. 77571/02 brought by Zambon Group SpA against Teva Pharmaceutical Industries Ltd., Milan, June 15, 2004, pp. 1-15.

Examiner	Date	
Signature	Considered	

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.